REMARKS

Claims 2-15 and 129-151 are pending in the present application.

By this amendment, claims 8, 137, and 138 are amended. Claims 8 and 137 are amended to overcome rejections and claim 138 is amended to assure proper antecedent basis. Support for these amendments can be found throughout the specification and claims as originally filed, for example at page 19 lines 4-7. No new matter has been introduced. With this amendment, claims 2-15 and 129-151 are pending. Applicants respectfully request reconsideration in view of the above amendments and following remarks.

Summary of Action

In the present action, claims 8 and 137 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 2, 4, 7, 10-13 and 130-151 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Baldwin, Gary, "System makes it easier to link patients to clinical trials" (hereinafter Baldwin" in view of information available at the website of CenterWatch (hereinafter CenterWatch) and Brown (USPN 6,196,970). Claims 3 and 129 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Baldwin, CenterWatch and Brown as applied to claim 2 above, and further in view of "TVisions wins Top Web Extranet Award; Recognized for Creative, Life-Saving Site" (hereinafter TVisions). Claims 5-6 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Baldwin, CenterWatch and Brown, as applied to claim 2, and in further view of Schmidt et al (USPN 6,839,687). Claims 8-9, and 14 stand rejected under 35 U.5.C. 103(a) as allegedly unpatentable over Baldwin, CenterWatch, and Brown, as applied to claim 2, and in further view of Official Notice. Claim 15 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Baldwin, CenterWatch and Brown as applied to claim 2 above, and further in view of Larkin, Marilynn, "Physicians accelerate onto the Internet" (hereinafter Larkin).

Response to BPAI Decision

The Office Action acknowledges that in the decision by the Board of Patent Appeals and Interferences (BPAI) mailed 1/31/06, the rejection of claims 2-15 and 129-151 was reversed. The Office Action states that the basis for reversal was, in substance, that Applicants should have been granted the benefit of the provisional priority date (January 28, 2000 from application 60/178,634) for the feature of "automatically presenting a questionnaire associated with the given clinical study to the person or caregiver." Thus, the Office Action acknowledges that the Knight reference, (USPN 2002/0099570) does not qualify as prior art under 35 U.S.C. 102(e) for the instant application. The Office Action has, however, provided new grounds of rejection for the pending claims.

Claim Rejections - 35 U.S.C. 112, second paragraph.

Claims 8 and 137 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, claim 8 recites that the notice is sent by "regular mail" and the Office Action alleges that it is unclear what the Applicants intend to claim or what the Applicants deem to be "regular mail." The Office Action asserts that for purposes of examination, any form of message delivery will be interpreted as "paper mail" and art will be applied accordingly. While Applicants disagree with the Office Action and assert that the meaning of "regular mail" is clear, to expedite prosecution of this application, Applicants have amended claim 8 to refer to "paper mail" rather than "regular mail."

Claim 137 recites "wherein said questionnaire requests information regarding inclusion/exclusion criteria." The Office Action alleges that the claim is vague and indefinite because it is unclear whether the "/" is "and" or "or." The Office Action asserts that for purposes of applying art, the slash will be interpreted as an "or." Applicants disagree that "inclusion/exclusion criteria" is indefinite but have nonetheless amended claim 137 to explicitly show that "inclusion/exclusion criteria" includes at least one of inclusion criteria, exclusion criteria, and combinations thereof.

In view of the foregoing amendments, it is respectfully requested that claims 8 and 137 meet the requirements of 35 U.S.C. 112, second paragraph. Thus, withdrawal of the rejections of claims 8 and 137 under 35 U.S.C. 112, second paragraph is respectfully requested.

Claim rejections – 35 U.S.C. 103(a)

I. Claims 2, 4, 7, 10-13 and 130-151

Claims 2, 4, 7, 10-13 and 130-151 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Baldwin in view of information available at the websites of CenterWatch and Brown.

A. Claim 2

Baldwin, CenterWatch, and Brown do not teach the elements that the Office Action claims they teach and the combination of the references is improper. However, even if the combination were permissible, the questions disclosed in Brown are presented *only if* and *only after* the person has enrolled in the clinical study. As such, a questionnaire could not possibly be presented <u>automatically</u> and <u>after step (d)</u>, as claim 2 requires. At the very least, Brown requires the intervening step of enrolling in a clinical study before any questionnaire might be presented. Since the intervening step of enrolling in a clinical trial is required, the questionnaire could not possibly be presenting <u>automatically after step (d)</u>.

The Office Action asserts that Baldwin discloses a steps (a) - (d) of claim 2, as recited below:

A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

- (a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;
- (b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;
 - (c) after step (b), automatically determining, in accordance with

the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person;

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice.

Baldwin discloses a closed system for tracking cancer studies (see e.g. ¶12 "[T]he new system keeps tabs on which trials have closed"). The system of Baldwin enables physicians—and only certain physicians whose practices are administered by American Oncology Resources—to identify ongoing clinical trials in oncology that may be appropriate for their patients. In this regard, Baldwin does not disclose the elements of the invention stated above for several reasons.

Baldwin never mentions registering any data; that is, there is no indication in Baldwin that a patient or caregiver is ever "registered" in the AOR database. Instead, Baldwin describes entering patient information, such as "age, sex, type of cancer, and nature of treatment," and comparing such against data stored in the AOR database. Thus, Baldwin describes running a data query, and nothing more. Notably, Baldwin makes no mention, for example, of the AOR system storing the entered information or later accessing such information in the event that future trials may be of interest to the patient.

Additionally, Baldwin does not teach that "the registration information includes ... at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies" as recited in independent claim 2. For example, Baldwin makes no mention of either the caregiver and/or the patient providing contact information and permission information. Simply put, Baldwin fails to even suggest providing registration information that includes "at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies" as recited in independent claim 2.

Baldwin also does not disclose "automatically registering the person or caregiver with the database upon receipt of the registration and permission information" as recited in independent claim 2.

Furthermore, Baldwin does not disclose, "after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person," as recited in independent claim 2. Although the system in Baldwin appears to make some determination of possible eligibility, this determination is based, at most, on the patient's "age, sex, type of cancer, and nature of treatment." The determination in Baldwin cannot be based on contact information or permission information as required in claim 2, because Baldwin does not disclose entering contact information or permission information into the system.

The Office Action states that "Baldwin does not disclose wherein the registration information includes at least a geographic location of the person." The Office Action asserts that "CenterWatch discloses wherein the registration information includes at least a geographic location of the person (i.e. Patient Notification Service pages)" and contends that "[i]t would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of Baldwin with the teaching of CenterWatch to include the collection of geographic location in the registration information of the person for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials."

The Office Action further asserts that the combination of Baldwin and CenterWatch do not explicitly disclose steps (e) and (f) of independent claim 2 (i.e., "(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and (f) storing answers submitted by the person or caregiver in the database."), but that Baldwin does disclose that after the patient has enrolled in a trial, the online system manages additional data collection and reporting and that Brown discloses automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d). The Office Action claims that Brown also discloses storing answers submitted by the person or caregiver in the database.

As explained above, contrary to the assertions of the Office Action, Baldwin does not disclose the elements of steps (a) - (d) of claim 2. The Office Action does not claim that

CenterWatch and Brown supply the deficiencies of Baldwin in regard to steps (a) - (d) of claim 2. CenterWatch generally discloses a "Clinical Trials Listing Service" (CenterWatch Home Page). Brown generally discloses a method and system by which research data can be collected and analyzed during the course of research testing (Brown, abstract).

Moreover, Baldwin, CenterWatch, and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in independent claim 2. It is well established that for two or more art references to be combined and used to render an invention obvious, there must be some motivation to combine them. In re: Jones, 958 F.2d 347 (Fed. Cir. 1992). Moreover, Applicants submit that the combination of Baldwin and CenterWatch is improper because the database of Baldwin would be inoperable with the CenterWatch system without some modification being made to it. Baldwin's database is a secure extranet that is open only to select users, including clinicians, drug companies, and administrator (Baldwin ¶ 23). Indeed, such a restricted system by its very nature cannot be used by patients themselves who are seeking information about clinical trials. CenterWatch, on the other hand, is intended to inform potential participants of available clinical studies, and enable them to begin a dialogue with the enrolling physician, similar to a computerized classified advertisement. Thus, in order to use the database techniques of CenterWatch in the system of Baldwin one would need to modify those database techniques so that they would be accessible by all users over the internet. The Examiner has no writing before her – other than Applicants' disclosure – that even arguably suggests such a modification. In fact, Baldwin itself teaches away from such a modification by limiting the access to "select users." The mere fact that the prior art could be modified would not have made the modification obvious unless the prior art

¹ Applicants object to the use of the CenterWatch material as prior art. The CenterWatch reference cited purports to be printouts of cached web pages. The dates of the printouts are November and December of 2002. While the printouts include various copyright dates earlier than 2002, it is impossible to know whether the content of the web site contained in those printouts has been altered since the copyright date. Applicants note that, unlike a book or other publication, the content of a website is easily amended and is typically amended with no indication on the face of the website what changes have been made. Further, the printout has no publication number or any other publicly accessible reference number. The public, and therefore the Examiner, cannot be sure how much of the subject matter contained in the printouts was publicly available before November of 2002. The status of this document as prior art, at least in the form printed in November or December of 2002, has therefore not been demonstrated. Applicants accordingly submit that it is improper for the Examiner to apply it against the pending claims and respectfully request that the Examiner withdraw all rejections relying on the CenterWatch printouts.

suggested the desirability of the modification itself. *In re: Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

Even if the database in Baldwin were altered to be useful in the present invention, it would no longer be operable for its originally intended purpose. Altering Baldwin to be open to the public would invalidate its intended purpose of requiring the patient's doctor to be the intermediary. As the Federal Circuit has noted, it is impermissible to use elements of a reference in formulating a rejection in a manner that would render them inoperable in their native environment. *In re: Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Indeed, such a reference is considered to teach away from such modifications. *Id.* In short, those of ordinary skill in the art simply would not combine the database of Baldwin with the system of CenterWatch. That combination therefore cannot render the claims unpatentable. Accordingly, Applicants assert that the combination of Baldwin and CenterWatch is improper. Thus, it is respectfully submitted that Baldwin, CenterWatch and Brown fail to teach or suggest the invention of independent claim 2. Therefore, withdrawal of the rejection of independent claim 2 under 35 U.S.C. § 103(a) is respectfully requested.

B. Claim 4

Regarding claim 4, which depends from independent claim 2, the Office Action asserts that "Baldwin and CenterWatch do not disclose the method of claim 2, wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study."

The Office Action asserts that "Brown discloses a method wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study" and provides "a method wherein protocol feedback (i.e. including questionnaire responses) allow researchers to determine whether a subject or given population is responsive to the treatment in a study or if a new population should be targeted (i.e. new patients are eligible)."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 4 is distinguishable

over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 4 recites.

Brown fails to disclose a method for determining whether the person is eligible for the given clinical study. Brown deals with a protocol for assembling data on patients already enrolled in a clinical study, as opposed to those used to determine whether the patient should be a participant in the first place. In other words, Brown only discloses events and questioning that occur during a clinical trial. The questions in Brown are not used to determine whether a person "is an eligible subject for" a particular study, as required by claim 4. Indeed, the person in Brown for whom the data is entered is already a subject in a clinical study. In fact, since the questions in Brown are only relevant to current study participants, and the current study participants are well past the eligibility stage, Brown teaches away from asking questions that would be used to determine eligibility because Brown is directed to a different problem. The Office Action implies, at page 7 paragraph 2, that Brown somehow discloses eligibility of new patients ("i.e. new patients are eligible"). On the contrary, Brown does not state or imply that "new patients are eligible." Brown only states that "[t]he researcher can also identify specific subgroups among the population of subjects, initiate new lines of inquiry and test new subhypotheses that may be raised by the incoming data" (see col. 6, lines 33-37). In any event, even if Brown did disclose eligibility requirements of new patients, it does not disclose a questionnaire including this criteria and the new criteria by definition would not be the same as the criteria for the given clinical study.

Thus, Brown fails to supply the deficiencies of Baldwin and CenterWatch as set forth above. Moreover, Baldwin, CenterWatch, and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 4. Thus, it is respectfully submitted that Baldwin, CenterWatch, and Brown fail to teach or suggest the invention of dependent claim 4. Therefore, withdrawal of the rejection of dependent claim 4 under 35 U.S.C. § 103(a) is respectfully requested.

C. Claim 7

Regarding claim 7, which depends from independent claim 2, the Office Action asserts that "Baldwin discloses the method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 7 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2. Moreover, Baldwin, CenterWatch, and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in independent claim 7. Therefore, withdrawal of the rejection of dependent claim 7 under 35 U.S.C. § 103(a) is respectfully requested.

D. Claim 10

Regarding claim 10, which depends from independent claim 2, the Office Action asserts that "Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study."

The Office Action asserts that "Baldwin does disclose wherein a determination is made to provide the person or caregiver with the notice in step (c) as discussed previously and that CenterWatch discloses providing notice of clinical studies in accordance with a geographic location of the given clinical study." The Office Action thus concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include notice of clinical studies in accordance with a geographic location of the given clinical study as allegedly disclosed by CenterWatch within Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 10 is distinguishable over

Baldwin, CenterWatch, and Brown for at least the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 10 recites.

Additionally, as discussed above, Baldwin fails to disclose receiving registration and permission information, much less determining, based on such information, "whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person." In addition, CenterWatch fails to disclose providing notice of clinical studies in accordance with a geographic location of the given clinical study. CenterWatch makes no comment regarding the use of geographical location and certainly does not teach that such information is used to provide notice of clinical studies. Such information could be used for a variety of purposes (*i.e.* statistical information) and CenterWatch does not disclose its use. CenterWatch, on the other hand, is simply printouts of cached web pages that instruct users to enter certain information - it does not explain how each and every piece of information will be used.

Thus, CenterWatch fails to supply the deficiencies of Baldwin. Moreover, Baldwin, CenterWatch and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 10. Thus, it is respectfully submitted that Baldwin, CenterWatch and Brown fail to teach or suggest the invention of dependent claim 10. Therefore, withdrawal of the rejection of dependent claim 10 under 35 U.S.C. § 103(a) is respectfully requested.

E. Claim 11

Regarding claim 11, which depends from independent claim 2, the Office Action asserts that "Baldwin discloses the method of claim 2, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study (i.e. fuzzy matches. The Office Action interprets this feature to read on clinical trials that the person or caregiver does not match)."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 11 is distinguishable

over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 11 recites.

Additionally, Baldwin fails to disclose a determination <u>not</u> to provide information. The "fuzzy matches" that the Office Action refers to and "interprets ... to read on clinical trials that the person or caregiver does not match" result in <u>providing</u> information to the doctor - the complete opposite of the feature of claim 11. In claim 11, a determination is made <u>not</u> to provide the person or caregiver with notice of the given clinical study. In other words, Baldwin only discloses a determination to <u>provide</u> information; it does not disclose a determination <u>not</u> to provide information.

Thus, Baldwin fails to supply the limitations of dependant claim 11 as set forth above. Moreover, Baldwin, CenterWatch and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 11. Thus, it is respectfully submitted that Baldwin, CenterWatch, and Brown fail to teach or suggest the invention of dependent claim 11. Therefore, withdrawal of the rejection of dependent claim 11 under 35 U.S.C. § 103(a) is respectfully requested.

F. Claim 12

Regarding claim 12, which depends from independent claim 2, the Office Action asserts that "Baldwin discloses the method of claim 2, wherein in step (a) the registration information includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 12 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 12 recites.

Additionally, as discussed above, Baldwin fails to disclose registering the patient with the AOR database. In addition, Baldwin makes no mention of either the caregiver and/or the patient providing whether the person is interested in clinical study information, whether the person is

interested in new medical therapies, or whether the person is interested in participating in clinical studies. Simply put, Baldwin fails to even suggest providing registration information that "includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies." Baldwin, at most, mentions entering "age, sex, type of cancer, and nature of treatment," into the AOR database. In other words, Baldwin only discloses entering specific information - information different from the registration information of claim 12 - into the system to determine whether a clinical trial in the database matches the criteria entered.

Thus, Baldwin fails to supply the limitations of dependant claim 12 as set forth above. Moreover, Baldwin, CenterWatch and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 12. Thus, it is respectfully submitted that Baldwin, CenterWatch and Brown fail to teach or suggest the invention of dependent claim 12. Therefore, withdrawal of the rejection of dependent claim 12 under 35 U.S.C. § 103(a) is respectfully requested.

G. Claim 13

Regarding claim 13, which depends from independent claim 2, the Office Action asserts that "Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study."

The Office Action asserts that "Baldwin discloses wherein a determination is made to provide the person or caregiver with the notice in step (c) [and that] CenterWatch discloses providing a list of clinical study(ies) in accordance with a geographic location of a clinical study as discussed previously above (the Examiner interprets the geographic determination limitation to include the geographic location of the clinical trial the investigator is associated with)." The Examiner thus concludes that "[i]t would have been obvious to one of ordinary skill at the time of Applicant's invention to include the geographic location matching of CenterWatch with the determination step of Baldwin for the motivation of providing clinical trial matching information

for patients and research professionals interested in information on and/or participating in clinical trials."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 13 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 13 recites.

Applicants note that previous Office Actions mailed December 4, 2002 and June 3, 2003, stated that "[a]s to claim 13, CenterWatch ... do[es] not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step(c) in accordance with a geographic location of an investigator associated with the study (Office Action dated June 3, 2003 at page 28).

Further, and as discussed above in reference to claim 10, CenterWatch fails to disclose providing notice of clinical studies in accordance with a geographic location of the given clinical study. CenterWatch makes no comment regarding the use of geographical location. It does not teach that such information is used to provide notice of clinical studies in any respect, much less in accordance with a geographical location of a clinical trial with which the investigator is associated.

Thus, the combination of Baldwin and CenterWatch fails to supply the limitations of dependant claim 12 as set forth above. Moreover, Baldwin, CenterWatch and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 13. Thus, it is respectfully submitted that Baldwin, CenterWatch and Brown fail to teach or suggest the invention of dependent claim 13. Therefore, withdrawal of the rejection of dependent claim 13 under 35 U.S.C. § 103(a) is respectfully requested.

H. Claim 130-136

Regarding claims 130-136, which either directly or indirectly depend from independent claim 2, the Office Action states that "Baldwin, CenterWatch, and Brown disclose the method of

claim 2, [but that] Baldwin and CenterWatch do not explicitly disclose that questionnaire is a pre-examination questionnaire (e.g. screening questionnaire; pre-screening questionnaire)."

The Office Action asserts that "Brown discloses a method wherein questionnaires are administered and data are collected at various points throughout research trial process ... [and that] Brown [also] discloses that the research protocol maybe be modified, non-responders may be identified, and new subgroups within the subjects may be identified for alternate or different testing with different parameters." As such, the Office Action concludes that "the questionnaires provided to the patients may function as screening, pre-screening, and pre-examination questionnaires in identifying those who are not eligible (*i.e.* responding poorly to the protocol) or identifying those who will participate well or poorly in the trial (non-responsive or responsive to the questionnaires)."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claims 130-136 are distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claims 130-136 recites.

Additionally, as discussed in reference to claim 4, Brown fails to disclose questionnaires that aid in determining eligibility for the given clinical study. By definition, the questionnaires of claims 130-136 are used to determine a person's eligibility *prior* to participation in the given clinical trial (*e.g.* pre-examination questionnaire, screening questionnaire, pre-screening questionnaire, questionnaire ... designed for screening for clinically appropriate persons). The subjects discussed in Brown are currently enrolled in a clinical trial, and whatever questions they are answering are *not* used to determine eligibility. The Office Action notes that the data is collected at various points *throughout* the research trial process. The various questionnaires of claims 130-136 are presented *before* the person is enrolled in a research study. Even if the protocol of Brown included questions that could be used to identify subjects currently enrolled in a research study for alternate or different testing, the alternate or different testing by definition would not be associated with *the given* clinical study as required by step (e) of claim 2

("automatically presenting a questionnaire associated with <u>the given</u> clinical study to the person or caregiver...") (emphasis added).

Thus, Brown fails to supply the deficiencies of Baldwin and CenterWatch as set forth above. Moreover, Baldwin, CenterWatch and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in claims 130-136. Thus, it is respectfully submitted that Baldwin, CenterWatch and Brown fail to teach or suggest the invention of claims 130-136. Therefore, withdrawal of the rejection of claims 130-136 under 35 U.S.C. § 103(a) is respectfully requested.

I. Claim 137

Regarding claim 137,² which depends from independent claim 2, the Office Action asserts that "Baldwin, CenterWatch, and Brown disclose the method of claim 2" but notes that "Baldwin does not expressly disclose that the questionnaire included inclusion or exclusion criteria."

The Office Action asserts that "CenterWatch discloses a questionnaire that includes inclusion or exclusion criteria. The Office Action thus concludes that "[a]t the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin with the teaching of CenterWatch to include exclusion or inclusion criteria on a questionnaire." The Office Action states that "[o]ne would have been motivated to include this feature to avoid wasting resources pursuing individuals who may no longer be interested in participating in a trial."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 137 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 137 recites.

Additionally, CenterWatch fails to disclose "wherein said questionnaire requests information regarding inclusion/exclusion criteria" as claim 137 requires. In fact, the previous

² The phrase "inclusion/exclusion criteria" has been amended in claim 137, but Applicants note that newly amended claim 137 has exactly the same scope as the prior version of claim 137.

Office Action mailed June 3, 2003, stated that "[a]s to claim 137, CenterWatch ... do[es] not explicitly disclose the method of claim 2, wherein said questionnaire requests information regarding inclusion/exclusion criteria" (Office Action dated June 3, 2003 at page 28).

Further, and as noted previously, there is no explanation given by CenterWatch for much of the information that it requests. It cannot be assumed that various pieces of information requested are exclusion/inclusion criteria.

Thus, CenterWatch fails to supply the deficiencies of Baldwin as set forth above. Moreover, Baldwin, CenterWatch and Brown do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 137. Thus, it is respectfully submitted that Baldwin, CenterWatch and Brown fail to teach or suggest the invention of dependent claim 137. Therefore, withdrawal of the rejection of dependent claim 137 under 35 U.S.C. § 103(a) is respectfully requested.

J. Claim 138-151

The Office Action rejects claims 138-151, under 35 U.S.C. 103(a) as being "substantially similar" to other rejected claims. In particular, the Office Action rejects claims 138 and 150 as being "substantially similar in scope to claim 131. As such, claims 138 and 150 are rejected for the reasons provided in the rejections of claims 2, 130, and 131, and incorporated herein." The Office Action rejects independent claims 139 and 140 because "the limitations of [such] ... claims are addressed by the rejection of independent claim 138." Regarding dependant claims 141-148, which directly or indirectly depend from independent claim 140, the Office Action asserts that such claims are "similar in scope to claims 130-137 and are rejected on the same basis." Regarding independent claims 149 and 151, the Office Action asserts that "the limitations of [such] ... claims are addressed by the rejection of claim 138."

Essentially, the Office Action is rejecting independent claims 138-140 and 149-151 and their dependencies, claiming that they are "substantially similar in scope" to independent claim 2 and its dependencies.³

³ The Office Action states that claims 138 and 150 are substantially similar is scope to claim 131 and that the limitations of claims 139 and 140 and claims 149 and 151 are addressed by the rejection of claim 138. Claim 131 is a dependent claim of independent claim 2.

To the extent that <u>certain elements</u> of claims 138-151 are similar in scope to <u>certain</u> <u>elements</u> of claim 2 and its dependencies, Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2 and its dependent claims, <u>for those elements that are similar in scope</u>, and submit that claims 138-151 are distinguishable over Baldwin, CenterWatch, and Brown for the reasons previously stated.

Applicants asserts, however, that independent claims 138-140 and 149-151 (and by extension dependant claims 141-148) are <u>not</u> "substantially similar" to claim 2 or any of its dependencies.

In particular, claim 138, step (a), requires "presenting at least one web page to permit an individual to be registered with a database by indicating whether the individual wishes to receive notice of one or more clinical studies and registration information ..." (emphasis added). Further, step (d) requires "...automatically determining in accordance with the indicating information, whether to provide... notice ..." (emphasis added).

Claim 139, step (a), requires "at least one web page to permit an individual *to be* registered with a database by submitting information *indicating* whether notice of one or more clinical studies is desired and registration information ..." (emphasis added).

Claim 140, step (a), requires "storing in a computer memory information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired and registration information ..." (emphasis added).

Claim 149, step (a), requires "storing in a computer memory information indicating whether notice of one or more clinical studies is desired and registration information ..." (emphasis added).

Claim 150, step (a), requires "providing information relating to at least one web page to permit an individual *to be registered* with a database by submitting information *indicating* whether notice of a clinical study is desired ..." (emphasis added).

Claim 151, step (a), requires "providing a web interface *for registering* an individual with a database by submitting information *indicating* whether notice of one or more clinical studies is desired and registration information ..." (emphasis added).

The Office Action does state where Baldwin, CenterWatch, or Brown teach anything about permitting an individual to be registered with a database based on *indicating* or *submitting information indicating* interest in receiving notice or where Baldwin teaches anything about storing in a computer memory information *indicating* whether notice is desired. Likewise the Office Action does not state where Baldwin, CenterWatch, or Brown teach automatically determining, *in accordance with the indicating information* and the registration information, whether to provide the individual with notice" Indeed Baldwin, CenterWatch, and Brown do *not* disclose these required elements. Therefore, withdrawal of the rejection of claims 138-151 under 35 U.S.C. § 103(a) is respectfully requested.

II. Claims 3 and 129

The Office Action rejects dependent claim 3 (which depends from independent claim 2), and independent claim 129 (which, according to the Office Action, the limitations such are "substantially similar to claim 2 with the exception of "step e), under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch, and Brown, as applied to claim 2, and in further view of TVisions.

Regarding claim 3, the Office Action asserts that "Baldwin, CenterWatch, and Brown do not explicitly disclose the method of claim 2, further comprising the step of: (g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f)."

The Office Action asserts that "TVisions discloses accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f)." The Office Action asserts that "[i]t would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to include accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) as disclosed by TVisions within Baldwin, CenterWatch and Brown for the motivation of alerting

physicians within seconds of possible matches of their patients with available or new clinical trials."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 3 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 3 recites.

TVisions discloses an "Extranet that empowers oncologists around the country to efficiently match their cancer patients with active clinical drug trials." (see TVisions ¶ 3)

TVisions fails, however, to disclose "to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f)." Instead,

TVisions discusses that "additions and updates to the patient profile database and the clinical trial databases activates the SecureNet Trial Matching System" but says nothing about determining whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

Additionally, although the Office Action states that there was a "motivation of alerting physicians within seconds of possible matches of their patients with available or new clinical trials," TVisions provides no such teaching. In fact, TVisions never states that physicians are alerted with new clinical trials — TVisions only says that "[o]ncologists are alerted within seconds of possible matches, and can provide more viable options of treatment for their patients" (see TVisions, ¶4).

Moreover, dependent claim 3 recites "(g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f)." The Office Action states that the motivation includes alerting physicians within seconds of possible matches...." TVisions does not teach that the person was interested in new clinical studies. Therefore, there would be no motivation to alert a patient within seconds of new clinical trials if the person never expressed an interest in the first place.

In view of the forgoing, TVisions fails to supply the deficiencies of Baldwin, CenterWatch, and Brown as set forth above. Thus, the combination of Baldwin, CenterWatch, Brown, and TVisions fails to provide the invention recited in dependent claim 3 as discussed above. Moreover, Baldwin, CenterWatch, Brown, and TVisions do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 3. Thus, it is respectfully submitted that Baldwin, CenterWatch, Brown, and TVisions fail to teach the invention recited in dependent claim 3. Therefore, withdrawal of the rejection of dependent claim 3 under 35 U.S.C. § 103(a) is respectfully requested.

Regarding independent claim 129, the Office Action asserts that "the limitations of [independent] claim 129 are substantially similar to [those of independent] claim 2 with the exception of 'step e." The Office Action states that "Baldwin, CenterWatch, and Brown do not disclose (e) allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site."

The Office Action asserts that TVisions discloses "allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site." The Office Action concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include storing answers submitted by the person or caregiver in the database as disclosed by TVisions for the motivation of alerting physicians within seconds of possible matches of their patients with available clinical trials and new clinical trials."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that independent claim 129 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features independent claim 129 recites.

As noted above, TVisions discloses an "Extranet that empowers oncologists around the country to efficiently match their cancer patients with active clinical drug trials." TVisions, however, fails to disclose anything having to do with a subsequent visit to a website, which is an element of claim 129, step (e). Furthermore, claim 129 requires "allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site." The purported motivation of "alerting physicians within

seconds of possible matches of their patients with available clinical trials and new clinical trials" has nothing to do with allowing the person to amend registration information. Indeed, TVisions fails to disclose such functionality.

In view of the forgoing, TVisions fails to supply the deficiencies of Baldwin, CenterWatch, and Brown as set forth above. Thus, the combination of Baldwin, CenterWatch, Brown, and TVisions fails to provide the invention recited in dependent claim 129 as discussed above. Moreover, Baldwin, CenterWatch, Brown, and TVisions do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 129. Thus, it is respectfully submitted that Baldwin, CenterWatch, Brown, and TVisions fail to teach the invention recited in dependent claim 2. Therefore, withdrawal of the rejection of dependent claim 129 under 35 U.S.C. § 103(a) is respectfully requested.

III. Claims 5 and 6

The Office Action rejects dependent claims 5 and 6, which depend from independent claim 2, under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch, and Brown, as applied to claim 2, and in further view of Schmidt.

Regarding claim 5, the Office Action asserts that "Baldwin and CenterWatch [disclose] a method for registering caregivers or individuals online and via the World Wide Web for clinical trials." The Office Action further contends that Brown discloses "automatically generating questionnaires and storing data for a person or caregiver on a database." Regarding claim 6, which depends from dependant claim 5, which further depends from independent claim 2, the Office Action asserts that "Baldwin discloses the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site (Fig. 10 and Fig. 11)."

The Office Action notes, however, that "Baldwin, Brown and CenterWatch do not explicitly disclose the method of claim 2, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site."

According to the Office Action, "Schmidt discloses a method wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages ... and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site."

The Office Action argues that "[i]t would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of Baldwin, Brown, and CenterWatch in combination with the teaching of Schmidt to have steps (a) and (b) performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) include notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site." The Office Action further contends that "[a]s suggested by Schmidt, one would have been motivated to include these features to provide method and system for conducting medical studies which enables a simpler and more effective completion of the medical studies."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claims 5 and 6 are distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claims 5 and 6 recite.

Schmidt discloses "a computerized system for conducting medical studies" (see Schmidt, col. 1, lines 7-8). Schmidt fails, however, to disclose a method "wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages." First, Schmidt specifically states that patient data is only sent to the central server after patient eligibility is determined and the patient is enrolled in the study ("When the patient's Declaration of Participation is recorded, then the patient is enrolled in the proposed medical study and the patient data are finally made available to the central server....This guarantees that unnecessary patient data are not transmitted to the central server...") (col. 5, lines 6-13). In this way, Schmidt teaches away from performing steps (a) and (b) during a registration visit. Although the Office Action contends that Schmidt discloses notifying the person or caregiver of the given clinical study during a current or subsequent visit

of the person or caregiver to the web site, such fails to say anything about a <u>subsequent</u> visit to the website, much less anything about notification. At most, Schmidt discloses a medical facility receiving a query, but even then the query is received by the <u>medical location</u>, as opposed to the person or caregiver as required by claims 5 and 6.

Regarding claim 6, Applicants note that Baldwin does not mention anything about providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver. In fact, the Office Action cites figures 10 and 11 of Baldwin as disclosing "the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site" Applicants note that Baldwin does not include <u>any</u> figures, much less figures that teach the element noted above.

In view of the forgoing, Schmidt fails to supply the deficiencies of Baldwin, CenterWatch and Brown as set forth above. Thus, the combination of Baldwin, CenterWatch, Brown, and Schmidt fails to provide the invention recited in dependent claims 5 and 6 as discussed above. Moreover, Baldwin, CenterWatch, Brown and Schmidt do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claims 5 and 6. Thus, it is respectfully submitted that Baldwin, CenterWatch, Brown and Schmidt fail to teach the invention recited in dependent claims 5 and 6. Therefore, withdrawal of the rejection of dependent claims 5 and 6 under 35 U.S.C. § 103(a) is respectfully requested.

IV. Claims 8, 9 and 14

The Office Action rejects dependent claims 8 and 9, which depend from independent claim 2, under 35 U.S.C. 103(a) as being "unpatentable over Baldwin, CenterWatch, and Brown, as applied to claim 2, and in further view of Official Notice," but in doing so indicates that "Baldwin, CenterWatch, and Brown in combination do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is sent by "regular" mail or telephone to the person or caregiver."

In this regard, the Office Action asserts that "at time of the Applicants' invention, the telephone and 'paper mail' (i.e. snail mail) were old and well-known means of communicating requested information or notifications to individuals" and concludes, without more, that "[a]t the time of the Applicants' invention it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin, CenterWatch, and Brown in combination to have the notice of step (d) sent by regular mail or telephone to the person or caregiver."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claims 8 and 9 are distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claims 8 and 9 recite.

Notably, Claims 8 and 9 are directed toward using paper mail and the telephone to provide the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice. The cited section of Brown (i.e., col. 3, lines 7-8) instead refers to the need to aggregate and analyze <u>data from research and clinical studies</u> ... <u>during the time of trial or research</u> (Brown, col. 3, lines 1-4). Thus, Brown is concerned with the timely aggregation of data obtained during an ongoing clinical study – not with the notification of eligibility to patients (and caregivers) who are not otherwise already participating in such study.

As for the motivation "to include these features to facilitate the aggregation and analysis of data from remote sites," Brown not only fails to provide this motivation, but it teaches away from the use of paper mail and telephone as means for communication. An underlying theme of Brown is the collection of clinical study information in "real time" through the use of "servers" (e.g. "These advantages are achieved in embodiments of the invention in which a research subject enters data using a client device that is coupled to a server via a communication link" (col. 3, lines 60-63); "Frequently researchers or lab technicians enter their observation in a paper copy of a log book or lab notebook [and] [o]ften these results are entered near the end of an experiment. This practice makes it impossible for an investigator to evaluate the data or change the experimental design" (col. 2, lines 48-53); "Accordingly, there is a need to evaluate and respond to subject in real time" (col. 2, lines 66-67)). The need to use "real time" methods such

as servers in no way provides a motivation to use traditional and slower methods such as regular mail and telephone, and instead teaches away from the use of such methods.

Thus, it is respectfully submitted that Baldwin, CenterWatch, and Brown fail to teach the invention recited in dependent claims 8 and 9. Therefore, withdrawal of the rejection of dependent claims 8 and 9 under 35 U.S.C. § 103(a) is respectfully requested.

The Office Action rejects dependent claim 14, which depends from independent claim 2, under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch, and Brown as applied to claim 2, but in doing so indicates that "Baldwin, CenterWatch, and Brown fail to explicitly disclose the method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources."

In this regard, the Examiner takes "official notice" that "at the time of applicant's invention it was well known in the art to provide information by telephone, mail, fax, or other 'offline sources' such as hand delivery." The Office Action thus argues that "[i]t would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of Baldwin, CenterWatch and Brown in combination to allow the person or caregivers to communicate answers by alternate means purportedly because one would have been motivated to include the alternatives to provide the customer with customer preferred delivery methods particularly with highly sensitive information."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 14 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 14 recites.

In particular, Applicants respectfully disagree that submitting answers by telephone, regular mail, facsimile, and other off-line sources is obvious in view of the teaching of Baldwin, CenterWatch, and Brown alone or in combination. No basis has been provided for why, based on the teachings of Baldwin, CenterWatch, and Brown, it would have been obvious to use regular mail or telephone for a transaction that is otherwise completely electronic. Although the Office Action indicates that the purpose of using such media would be to provide the customers with preferred, convenient delivery methods (particularly for highly sensitive information), such a

conclusion is at odds with the teachings of Baldwin, CenterWatch, and Brown. Baldwin, CenterWatch, and Brown all deal with electronic systems and teach away from using traditional methods. In fact, convenience has dictated that correspondence *not* take place using telephone, regular mail, facsimile, and other off-line sources, but instead take place electronically. Indeed, the general trend in communications, especially communication using the Internet, is to have the entire transaction occur electronically, without any use of regular mail or telephone.

Thus, it is respectfully submitted that Baldwin, CenterWatch, and Brown fail to teach the invention recited in dependent claim 14. Therefore, withdrawal of the rejection of dependent claim 14 under 35 U.S.C. § 103(a) is respectfully requested.

V. Claim 15

The Office Action rejects dependent claim 15, which depends from independent claim 2, under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Brown, and further in view of Larkin. The Office Action asserts that "Baldwin and CenterWatch do not disclose the method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database."

The Office Action asserts that "Larkin discloses clinical studies directed to particular genetic sequences and using online recruitment." The Office Action thus concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the online patient recruitment of clinical studies for genetic studies within the Baldwin, CenterWatch and Brown in the method for the motivation of speeding up patient recruitment."

Applicants reiterate the remarks set forth above regarding Baldwin, CenterWatch, and Brown as applied to independent claim 2, and submit that dependent claim 15 is distinguishable over Baldwin, CenterWatch, and Brown for at least for the reasons set forth above regarding independent claim 2 as well as the additional features dependent claim 15 recites.

Additionally, Larkin fails to describe "wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database." Larkin's singe reference to "genetic studies" (paragraph 6) says nothing about using genetic sequence information associated with a person registered in the database. On the

other hand, "genetic studies" as used in Larkin implies that genetic sequence information of the person is not currently known, and thus could not be entered into the database by the person. In addition, Larkin says nothing about registration of a person with a database with or without genetic sequence information. Likewise, Larkin is silent of the feature of "automatically determining."

In view of the forgoing, Larkin fails to supply the deficiencies of Baldwin and CenterWatch as set forth above. Thus, the combination of Baldwin, CenterWatch, Brown, and Larkin fails to provide the invention recited in dependent claim 15 as discussed above. Moreover, Baldwin, CenterWatch, Brown, and Larkin do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in dependent claim 15. Thus, it is respectfully submitted that Baldwin, CenterWatch, Brown, and Larkin fail to teach the invention recited in dependent claim 15. Therefore, withdrawal of the rejection of dependent claim 15 under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants respectfully request the reconsideration and timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response; the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing matter number 16602.003.

Respectfully submitted,

Joseph A. Micallef (Reg. 39,772)

Danielle M. Edwards (Reg. 51,645)

Danielle Elwards

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ARNOLD & PORTER, LLP 555 12TH Street, N.W. Washington, D.C. 20004 (202) 942-5000 telephone (202) 942-5999 facsimile